

EXHIBIT 119

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE NORTHERN DISTRICT OF OHIO
3 EASTERN DIVISION
4 - - -
5

6 IN RE: NATIONAL : HON. DAN A.
7 PRESCRIPTION OPIATE : POLSTER
8 LITIGATION :
9 :
10 APPLIES TO ALL CASES : NO.
11 : 1:17-MD-2804
12 :
13

14 - HIGHLY CONFIDENTIAL -
15

16 SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
17 - - -
18

19 March 15, 2019
20 - - -
21

22 Videotaped deposition of
23 STEPHEN C. MACRIDES taken pursuant to
24 notice, was held at the offices of
 McCarter & English, LLP, 1600 Market
 Street, Philadelphia, Pennsylvania,
 beginning at 9:05 a.m., on the above
 date, before Michelle L. Gray, a
 Registered Professional Reporter,
 Certified Shorthand Reporter, Certified
 Realtime Reporter, and Notary Public.

 - - -
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1 A. There's growth.

2 Q. Okay. And let's see, how
3 did we do from 2000 to 2001, sir?

4 Doing better?

5 MS. VANNI: Object to form.

6 BY MR. BUCHANAN:

7 Q. Selling more?

8 MS. VANNI: Objection.

9 THE WITNESS: We're shipping
10 more product to patients who need
11 them.

12 BY MR. BUCHANAN:

13 Q. Okay. 500 plus million,
14 half a billion pills; is that right?

15 A. 516 million.

16 Q. Okay.

17 MS. VANNI: Also note my
18 objection that he is not a
19 30(b)(6) on sales history.

20 BY MR. BUCHANAN:

21 Q. Okay. I believe, in fact,
22 you are a designee on suspicious order
23 monitoring, correct?

24 A. Correct.

1 Q. Okay. Each of the shipments
2 that are memorialized in shipping records
3 followed an order, right?

4 MS. VANNI: Object to form.

5 THE WITNESS: You need an
6 order to ship a product.

7 BY MR. BUCHANAN:

8 Q. Understood. Since the
9 beginning of Endo's existence, Endo has
10 been charged with maintain -- maintaining
11 effective controls against diversion,
12 correct?

13 MS. VANNI: Object to form.

14 THE WITNESS: The
15 regulations state that we need to
16 have controls to prevent
17 diversion.

18 BY MR. BUCHANAN:

19 Q. Not just any controls,
20 right?

21 A. Can you clarify what you
22 mean by that?

23 Q. You have to have effective
24 controls, right?

1 A. Yes. We have to have
2 controls in place to prevent diversion.

3 Q. You have to have -- what's
4 the word you dropped?

5 MS. VANNI: Object to form.

6 BY MR. BUCHANAN:

7 Q. Effective controls, right?

8 A. That those controls should
9 be effective.

10 Q. That's right.

11 A. I don't disagree with you.

12 Q. Okay. So from the
13 beginning, from 1999 till today, Endo has
14 been responsible for ensuring it has
15 effective controls to prevent diversion,
16 correct?

17 A. By the regulations, that's
18 what we need to do.

19 Q. As a reasonable company,
20 that's what you need to do --

21 MS. VANNI: Object to form.

22 BY MR. BUCHANAN:

23 Q. -- right?

24 A. We have a responsibility to

1 Q. Okay. There's an operating
2 company known as Endo, right?

3 A. Right.

4 Q. That line of business
5 includes the company's branded portfolio;
6 is that accurate?

7 A. That would be accurate.

8 Q. Okay. There's an operating
9 company known as Par today?

10 A. Correct.

11 Q. Just owned by the Irish Endo
12 entity, correct?

13 A. Correct.

14 Q. Par today owns what used to
15 be Endo's generic business, as well as
16 what used to be called Qualitest's
17 business, correct?

18 MS. VANNI: Object to form.
19 He's also not a corporate designee
20 on corporate structure, corporate
21 history.

22 BY MR. BUCHANAN:

23 Q. And I'm really not trying to
24 do that, you know, for a legal purpose.

1 I just want to make sure we're clear in
2 communicating today, because it could get
3 confusing.

4 A. What I can tell you is Par
5 had a generics business. Endo had a
6 generics business that it operated as
7 Qualitest. Par and Qualitest were merged
8 into a single generics business that now
9 operates under the Par name.

10 Q. Okay. So the current -- the
11 current generics business is all under
12 the Par name. Is it in the Par entity?

13 MS. VANNI: Object to form.

14 THE WITNESS: I'm not an
15 expert on our legal entity
16 structure. Our generics business
17 operates under the Par name.

18 BY MR. BUCHANAN:

19 Q. Okay.

20 A. That's what I can tell you.

21 Q. We have named Par and we
22 have named Endo.

23 A. Right.

24 Q. I want to know when I talk

1 MS. VANNI: Object to form.

2 THE WITNESS: There -- there
3 are other regulations, controls,
4 that we follow that would more be
5 under the category of suspicious
6 order monitoring when it comes to
7 DEA compliance, to ensure that
8 orders are properly reviewed,
9 investigated before they are
10 distributed.

11 BY MR. BUCHANAN:

12 Q. Okay. And that's what I
13 wanted to understand.

14 So the concern that you have
15 and the care you have to take with
16 handling this product in the warehouse or
17 handling this product in manufacturing
18 with your own employees, people who you
19 trust and hire, has to be exercised in
20 investigating, in reviewing, every single
21 order you receive, because that concern
22 doesn't stop in the warehouse, right?

23 MS. VANNI: Object to form.

24 THE WITNESS: The control --

1 the proper control of these
2 products extends throughout the
3 supply chain.

4 BY MR. BUCHANAN:

5 Q. Right. So when the company
6 receives an order for one of its
7 controlled products, it has an obligation
8 to maintain effective controls against
9 diversion with regard to the orders it
10 receives, right?

11 MS. VANNI: Object to form.

12 THE WITNESS: We have a
13 responsibility under the
14 regulations to make sure that we
15 are reviewing orders, that we are
16 understanding any orders of
17 interest, we are investigating
18 those. And if it comes to it, and
19 if we determine that the order is
20 suspicious, then not to ship that
21 order.

22 BY MR. BUCHANAN:

23 Q. Okay. So we were looking at
24 the Endo orders just a moment ago, just

1 to give us some context. I believe it's
2 Exhibit 4.

3 Let's look at 1999. You
4 know, shipped -- shipped hundreds of
5 millions of opioid products in 1999.
6 Every one of those was by an order.

7 And how many suspicious
8 orders did the company report to the DEA
9 in 1999 for Endo products, sir?

10 MS. VANNI: Object to form.
11 The colloquy.

12 THE WITNESS: I don't
13 believe we reported any suspicious
14 orders as an outcome of our
15 investigations.

16 BY MR. BUCHANAN:

17 Q. Okay. So in 1999 the
18 company reported no suspicious orders to
19 the DEA for Endo's orders?

20 A. I don't believe we reported
21 any suspicious orders to the DEA in 1999
22 as a result of our investigations.

23 Q. Okay. How about in 2000,
24 we've got, you know, hundreds of millions

1 of pills again, 400 million plus. I
2 guess that's also syrups, so dosage units
3 of syrups.

4 400-plus million pills and
5 dosage units all pursuant to orders. And
6 how many suspicious orders did -- did
7 Endo report to the DEA for 2000?

8 MS. VANNI: Object to form.

9 THE WITNESS: I don't
10 believe we reported any suspicious
11 orders in 2000 as an outcome of
12 our investigations into anything
13 that was of interest.

14 BY MR. BUCHANAN:

15 Q. Okay. How about 2001, it
16 looks like -- well, sales are growing.
17 We talked about that a moment ago.
18 500-plus million pills and dosage units
19 for Endo in 2001.

20 How many suspicious orders
21 got reported to the DEA that year?

22 MS. VANNI: Object to the
23 colloquy. You can answer.

24 THE WITNESS: I don't

1 believe we reported any suspicious
2 orders to DEA after the outcome of
3 our invest -- as an outcome of our
4 investigations into anything that
5 was of interest.

6 BY MR. BUCHANAN:

7 Q. Oh. Okay. So thousands and
8 thousands and thousands of orders, right?

9 A. We had orders. I can't tell
10 you specifically how many orders we had.
11 But we had orders that represented these
12 quantities.

13 Q. Okay. That -- that on an
14 annual basis would give every American an
15 opioid, right?

16 MS. VANNI: Object to form.

17 THE WITNESS: We got
18 order -- we received orders for
19 opioids from our customers who in
20 turn sold them to patients who
21 needed them.

22 BY MR. BUCHANAN:

23 Q. And not one suspicious order
24 was reported to the DEA in 2001?

1 A. We did not report any
2 suspicious orders to DEA after
3 investigating internally any orders that
4 we deemed as of interest.

5 Q. Okay. How about 2002?
6 Sales still on the move. Growing along,
7 I guess we can pull out our -- our death
8 map that we looked at a moment ago. We'd
9 see the deep blue going to lighter blue,
10 going to tan and yellow, and more people
11 dying.

12 How many suspicious orders
13 did you report to the DEA in 2002?

14 MS. VANNI: Objection.

15 THE WITNESS: I don't
16 believe we reported any orders,
17 suspicious orders to DEA as an
18 outcome of our internal
19 investigations into any orders of
20 interest.

21 BY MR. BUCHANAN:

22 Q. Okay. 2003, sales still on
23 the move, right? We are back on
24 Exhibit 4.

1 800 million pills, opioids,
2 dosage units in 2003. All pursuant to
3 orders the company received, right?

4 MS. VANNI: Object to form.

5 THE WITNESS: Yes. We would
6 receive orders to represent those
7 quantities shipped.

8 BY MR. BUCHANAN:

9 Q. Okay. And how many of those
10 did the company identify as suspicious?

11 A. I don't believe we reported
12 any suspicious orders to the DEA as an
13 outcome of our internal investigations
14 into any orders of interest.

15 Q. Okay. So you didn't report
16 any over this period of time as we just
17 looked at a five-year window.

18 How many did you not ship?

19 A. I don't believe we
20 ultimately -- we ultimately shipped all
21 of these orders as an outcome of our
22 internal investigations into any orders
23 of interest.

24 Q. Okay. So you've got a drug

1 issues through our suspicious order
2 monitoring system. That's my answer.

3 Q. Not a single one was ever
4 reported to DEA?

5 A. If an order had been
6 determined to be suspicious, it would
7 have been reported to DEA.

8 Q. As a numbers matter, sir,
9 just stay with my question.

10 Did the company ever report
11 any order that Endo received for any of
12 its opioid products over the period of
13 time, 1999 to present to the DEA as a
14 suspicious order?

15 MS. VANNI: Object to form.

16 THE WITNESS: If an order
17 was deemed suspicious --

18 BY MR. BUCHANAN:

19 Q. Did the company ever do it?

20 A. If the order was -- if an
21 order was deemed suspicious, it would
22 have been reported to the DEA.

23 Q. It doesn't answer my
24 question. I just want the fact. Not an

1 BY MR. BUCHANAN:

2 Q. I'm passing you, sir, what
3 we're marking as Exhibit 8 to your
4 deposition.

5 MS. VANNI: Thank you.

6 BY MR. BUCHANAN:

7 Q. Sir, you'll recall before
8 the break we were talking about your
9 awareness or not of Endo's products being
10 diverted. Do you recall that?

11 A. I recall that.

12 Q. Okay. Showing you what is
13 an e-mail from Mr. Barto to Ms. Connell
14 from 2003, subject revised DEA meeting
15 minutes. Do you see that?

16 A. I see it.

17 Q. Okay. Who's Mr. Barto?

18 A. I believe he was a former
19 employee of Endo.

20 Q. You recognize him as being
21 in regulatory affairs for Endo?

22 A. It says here that he worked
23 in regulatory affairs.

24 Q. Okay. Ms. Connell, you

1 recognize her as being on the supply
2 chain side?

3 A. I do.

4 Q. Okay. In connection with
5 your preparation, sir, were you aware
6 that the company sat down with the DEA in
7 2003 to discuss abuse and diversion
8 measures with regard to Endo's products?

9 MS. VANNI: Object to form.

10 THE WITNESS: In 2003?

11 BY MR. BUCHANAN:

12 Q. Mm-hmm.

13 A. I was aware that Endo had
14 discussions with DEA during the time
15 period that we are talking about.

16 Q. Okay. I'll pass you, sir,
17 Exhibit 9 to your deposition.

18 (Document marked for
19 identification as Exhibit
20 Endo-Macrides-9.)

21 BY MR. BUCHANAN:

22 Q. Is that a yes answer, that
23 you're aware that the company had
24 discussed abuse and diversion of Endo's

1 oxycodone/APAP. All three of those are
2 essentially the same pharmaceutical
3 combination, they just get marketed in
4 different ways, right?

5 MS. VANNI: Objection.
6 Beyond the scope.

7 THE WITNESS: Some are
8 branded and some are generic.

9 BY MR. BUCHANAN:

10 Q. Fair. I mean, I wasn't
11 trying to be tricky with that. I just
12 wanted to -- the company, for whatever
13 its business reasons over time, has used
14 different trade names or branded names
15 for the same pharmaceutical combination,
16 true?

17 MS. VANNI: Object to form.

18 THE WITNESS: The branded
19 name is Percocet. And then there
20 are generics that go by different
21 names.

22 BY MR. BUCHANAN:

23 Q. Okay. All right, good. So
24 Percocet in abuse and diversion was a big

1 deal into the early 2000s; isn't that
2 right?

3 MS. VANNI: Objection.

4 THE WITNESS: I don't have
5 specific knowledge on Percocet
6 abuse because --

7 BY MR. BUCHANAN:

8 Q. Sorry.

9 A. Well, as I stated earlier,
10 if our products aren't properly
11 controlled, if they get out of the closed
12 system, then they have -- they can be
13 abused and diverted.

14 Q. Okay.

15 MR. BUCHANAN: Can we pull
16 up the chart for the first --
17 let's just say through 2003,
18 please.

19 There you go.

20 BY MR. BUCHANAN:

21 Q. All right. So we can see
22 that in fact Percocet, Endocet, and
23 oxycodone/APAP -- let's get the Percocet
24 up there. Those are big movers for the

1 company in the early -- late '90s, early
2 2000s, right?

3 MS. VANNI: Object to form.

4 THE WITNESS: Can you
5 clarify what you mean by "big
6 mover"?

7 BY MR. BUCHANAN:

8 Q. I guess, for simplicity,
9 two-thirds of your sales?

10 A. We were shipping Percocet
11 and Endocet based on orders from our
12 customers based on patient demand.

13 Q. I understand that, sir. But
14 looking at the chart so we have some
15 rough sense of what the business
16 represented, about two-thirds of sales,
17 at least in terms of pills, was Percocet
18 or Percocet-like formulations, correct,
19 sir?

20 MS. VANNI: Object to form.

21 THE WITNESS: Yes, based
22 on -- if we're looking at 1999, a
23 majority of the tablets shipped
24 were Percocet or Endocet.

1 BY MR. BUCHANAN:

2 Q. Right. And roughly, what is
3 that, 260 million pills, Percocets,
4 versus a total of 360 or so?

5 A. Right.

6 Q. Okay. And excuse my
7 rounding. I'm just trying to make it
8 faster and simpler for both of us.

9 All right. We go forward in
10 2000. And you're, you know, again, at
11 roughly 340 million of 450 million pills
12 are the Percocet and Endocet drugs,
13 right?

14 MS. VANNI: Object to form.

15 THE WITNESS: That's what it
16 says.

17 BY MR. BUCHANAN:

18 Q. Percocet was Endo's brand?

19 A. Percocet was a branded
20 product or is a branded product.

21 Q. But the brand Percocet, was
22 that Endo's brand name?

23 A. It was.

24 Q. They owned it?

1 MS. VANNI: Object to form.

2 THE WITNESS: Correct.

3 BY MR. BUCHANAN:

4 Q. So when the jury or consumer
5 hears Percocet, they should think of
6 Endo?

7 MS. VANNI: Object to form.

8 BY MR. BUCHANAN:

9 Q. Right?

10 A. Percocet is the brand.

11 Q. That's the name you marketed
12 it under, right?

13 A. That's the name that Endo
14 marketed the product under, Percocet.

15 Q. And if we looked at Percocet
16 pills shipped by Endo, we'd see a little
17 R with a circle around it, right?

18 It was your registered trade
19 name for it, correct?

20 A. It was.

21 Q. You had the exclusive right
22 to use that name, right?

23 MS. VANNI: Object to form.

24 Beyond the scope.

1 THE WITNESS: From a
2 regulatory perspective, yes.

3 BY MR. BUCHANAN:

4 Q. Right. So when the jury
5 hears Percocet it can think Endo, right?

6 MS. VANNI: Objection.

7 BY MR. BUCHANAN:

8 Q. It has your name?

9 MS. VANNI: Objection.

10 THE WITNESS: Percocet was
11 our branded product. I will say
12 though, that as a strip that you
13 put on a cut, it's called a
14 Band-Aid, there is a branded
15 Band-Aid. And there are a lot of
16 other kinds of band-aids.

17 There is a branded Percocet
18 product and there are a lot of
19 generic Percocet products. Some
20 distributed by Endo, some
21 distributed not by Endo.

22 So there are a number of
23 products, generic products, that
24 get referred to as Percocet, that

1 may or may not be the branded
2 Percocet.

3 BY MR. BUCHANAN:

4 Q. Fair point, sir.

5 And we see, in fact, you
6 sold a generic version of your own
7 branded product, right?

8 A. We did.

9 Q. Right. Well, we can't
10 dispute that -- or you don't dispute, do
11 you, sir, that you sold a lot of
12 Percocet?

13 MS. VANNI: Object to form.

14 BY MR. BUCHANAN:

15 Q. And its generic equivalence?

16 MS. VANNI: Object to form.

17 THE WITNESS: We sold
18 Percocet. I'm not disputing that.

19 BY MR. BUCHANAN:

20 Q. Okay. And as we see through
21 the years, certainly the early years
22 here, sir, Percocet is a big part of your
23 sales portfolio, right?

24 MS. VANNI: Object to form.

1 THE WITNESS: We sold the
2 quantities of Percocet that are
3 listed on this sheet.

4 BY MR. BUCHANAN:

5 Q. Okay. So by 2003, wow, you
6 have taken, with your Percocet and
7 Endocet brand, you've gone from, what,
8 about 260 million pills of Percocet and
9 Endocet in 1999, to, what is that, about
10 640 million pills, of Percocet and
11 Endocet for one year in 2003?

12 A. About that.

13 Q. Just about doubled, five
14 years.

15 A. Right. Reflecting the
16 demand for the product, for the patients
17 that need it.

18 Q. A lot of growth, agreed?

19 MS. VANNI: Object to form.

20 BY MR. BUCHANAN:

21 Q. Doubled sales in five years
22 of Percocets?

23 A. There's growth from 1999 to
24 2003 reflecting the increased demand for

1 specific input to challenge us and
2 to give us suggestions on how we
3 can improve.

4 BY MR. BUCHANAN:

5 Q. Sure.

6 A. In that context that's why
7 we -- that's how we would have --

8 Q. And you invited them into
9 your shop, right?

10 MS. VANNI: Object to form.

11 BY MR. BUCHANAN:

12 Q. Per the 1056.3?

13 A. I'm just looking this over.
14 Yes, it looked like there was a visit to
15 the facility.

16 Q. Visit to the facility, short
17 review of documents, to provide findings
18 and recommendations back to the company,
19 correct? We're going to 1056.10.

20 A. 1056.10?

21 Q. Yes. Is that correct? You
22 called them in. They looked at stuff.
23 They gave you a report and analysis back?
24 Fair, sir?

1 A. It looked like they did an
2 audit and gave us some -- some findings.

3 Q. Okay. Let's go to Finding
4 Number 8.

5 A. Are you on --

6 Q. 1056.10.

7 A. Okay.

8 Q. I'm sorry.

9 Finding Number 8, SOM,
10 below. I guess there's two Finding
11 Number 8 -- Findings Number 8.

12 Finding Number 8, SOM.
13 Could you read that sentence for us, sir?

14 A. "There is no suspicious
15 order monitoring program in place."

16 Q. Okay. Let's pause there.
17 As of 2010, the company is selling
18 controlled substances that it must keep
19 in a vault and in a cage in its warehouse
20 and production facilities, correct?

21 MS. VANNI: Object to form.

22 THE WITNESS: Par was
23 selling opioids that had certain
24 regulations on how they needed to

1 be stored and controlled.

2 BY MR. BUCHANAN:

3 Q. And there is a requirement?

4 MR. BUCHANAN: Can we blow
5 that out?

6 BY MR. BUCHANAN:

7 Q. Under 21 C.F.R. 1301.74(b).
8 Do you see that? That the company must
9 maintain and operate a system to disclose
10 to the registrant suspicious orders of
11 controlled substances, right?

12 Do you see that?

13 A. Yeah. And if I could just
14 have a minute to read it. Yes, this is
15 what the regulation says.

16 Q. Okay. And that regulation's
17 not a new one, right?

18 A. No.

19 Q. I mean, that regulation has
20 been around for as long as Endo has been
21 around, right?

22 MS. VANNI: Objection.

23 THE WITNESS: The

24 regulations has been in place for

1 whatever period of time they've
2 been in place.

3 BY MR. BUCHANAN:

4 Q. Right. And the Controlled
5 Substance Act actually has a provision
6 that manufacturers and distributors are
7 supposed to maintain effective controls
8 against diversion, right? Are you aware
9 of that?

10 A. I'm aware of that, yes.

11 Q. Okay. So as of 2010, sir,
12 there is no suspicious order monitoring
13 program in place. That's what you're
14 told by the consultants you hired to look
15 at this issue, correct?

16 A. That's what the report says.

17 Q. Okay.

18 A. So as I said earlier, we
19 hired --

20 Q. That's my question sir.

21 Recommendation underneath,
22 "Although it was stated that sales are
23 mainly to large wholesalers" -- let's
24 pause.

1 As a registrant, you have an
2 obligation to maintain a suspicious order
3 monitoring program, period, correct, sir?

4 MS. VANNI: Object to form.

5 THE WITNESS: We have an
6 obligation to do what it says here
7 in the regulations, to design and
8 operate a system to disclose to
9 the registrant suspicious orders
10 of controlled substances.

11 BY MR. BUCHANAN:

12 Q. Right.

13 A. That's what we have an
14 obligation to do.

15 Q. Right. It doesn't -- the
16 explanation given to your consultant that
17 well, we just sell to wholesalers, that
18 doesn't mean that you don't have to have
19 a suspicious order monitoring program,
20 right?

21 MS. VANNI: Object to form.

22 THE WITNESS: We have to --

23 BY MR. BUCHANAN:

24 Q. You know better than that?

1 Q. Sitting here today, sir, you
2 don't recall a single Par policy,
3 procedure, or standard operating document
4 prior to the date of this memo for
5 suspicious order monitoring, correct,
6 sir?

7 MS. VANNI: Object to form.

8 THE WITNESS: I do recall a
9 suspicious order monitoring SOP.

10 I do not recall the time
11 frame at which that was
12 implemented.

13 BY MR. BUCHANAN:

14 Q. Okay. Well, we'll look at
15 that. Okay.

16 Because the company, a few
17 years later, implements an SOP, right?

18 MS. VANNI: Object to form.

19 BY MR. BUCHANAN:

20 Q. After it's been selling
21 opioids for years --

22 MS. VANNI: Objection.

23 BY MR. BUCHANAN:

24 Q. -- right?

1 MS. VANNI: Objection.

2 THE WITNESS: As I said, our
3 programs were evolving in response
4 to increasing our diligence around
5 monitoring orders and ensuring
6 that we were doing everything we
7 could within the regulations to
8 prevent our abuse and diversion.

9 This step of bringing in a
10 consultant, which we do quite
11 frequently, to challenge us, to
12 help us raise the bar, to give us
13 their view on things.

14 MR. BUCHANAN: Move to
15 strike.

16 BY MR. BUCHANAN:

17 Q. My question was, the company
18 has been selling opioids for years prior
19 to the time it implements its first SOP.

20 Do you know that, sir?

21 MS. VANNI: Objection.

22 Asked and answered.

23 THE WITNESS: I have data
24 here that says the company was

1 things, and delivered a report which said
2 there is no suspicious order monitoring
3 program in place as of this date in 2010,
4 correct, sir?

5 MS. VANNI: Object to form.

6 THE WITNESS: As the
7 consultants define suspicious
8 order monitoring program, their
9 input was we needed to enhance
10 whatever we were doing in terms of
11 looking at orders and formalize
12 the program. That's how I would
13 interpret their response here.

14 BY MR. BUCHANAN:

15 Q. Okay. And so the answer to
16 my question, sir, though about whether
17 you are aware of a standard operating
18 procedure for SOMs or a policy as of 2010
19 is still the same, you're not aware of
20 one, correct?

21 MS. VANNI: Objection.

22 Misstates his testimony.

23 THE WITNESS: I reviewed a
24 lot of documents. I know I

1 reviewed documents, Par documents,
2 that were related to suspicious
3 order monitoring.

4 I don't remember -- I don't
5 recall the date. I looked at a
6 lot of documents to prepare for
7 this. I didn't commit them all to
8 memory.

9 BY MR. BUCHANAN:

10 Q. Okay. Let me show you the
11 first one we found, sir. Okay.

12 MR. BUCHANAN: Can I have
13 1839.

14 (Document marked for
15 identification as Exhibit
16 Endo-Macrides-12.)

17 BY MR. BUCHANAN:

18 Q. I'm passing you, sir, what
19 we're marking as Exhibit 12. This is an
20 e-mail from Ms. Feniger to Ms. Lipari and
21 some others on the team. Suspicious
22 order monitoring.

23 SOM, do you see that?

24 A. I see that.

1 Q. Attachments SO002. Do you
2 see that?

3 A. I see that.

4 Q. Okay. The quality is
5 something we're both suffering with, sir.
6 I wish I could have given you a better
7 copy.

8 And so what we have here is
9 the SOM. And it's SOP number SO002.0.
10 Do you see that?

11 A. I see that.

12 Q. And it says supersedes.
13 What does it say after that?

14 MR. BUCHANAN: Can you go to
15 .2 please.

16 THE WITNESS: I'm sorry.

17 BY MR. BUCHANAN:

18 Q. I'm sorry. It's the top of
19 the page, sir. I know my question was
20 confusing.

21 We see the SOP number on the
22 right. You recognize that companies like
23 yours number their SOPs?

24 A. Right.

1 Q. And they often put a version
2 number, a dot after to indicate an
3 incremental change to an SOP?

4 A. Right.

5 Q. Okay. What's the title of
6 this particular SOP, sir?

7 A. Suspicious order monitoring.

8 Q. Okay. And the SOP number
9 for it is S0002.0, correct?

10 A. Correct.

11 Q. Supersedes?

12 A. It says not applicable.

13 Q. What is the date, the
14 effective date of this SOP, sir?

15 A. April 17th of 2012.

16 Q. Okay. And we've got
17 signatures and approvals written by,
18 checked by, approved by.

19 Do you see all that?

20 A. I do.

21 Q. Okay. This was actually
22 written by the head of sales?

23 A. Written by Patricia Lipari,
24 director of sales.

1 Q. Okay.

2 A. Sales operations.

3 Q. Okay. Sales ops. And it
4 was checked by a technical writer in
5 documentation, right?

6 A. Checked by, yeah, Angela
7 Feniger.

8 Q. I can't read the approved by
9 name. Do you know that name?

10 A. Dino Taraban.

11 Q. Okay. And so, sir, this
12 is -- the .0 or the first version of
13 Par's SOM, suspicious order monitoring
14 SOP, correct, sir?

15 A. Appears to be the first
16 specific SOP entitled suspicious order
17 monitoring.

18 Q. Okay. And --

19 A. But I wouldn't interpret
20 that as suggesting that orders were not
21 being looked at in some capacity prior to
22 that.

23 Q. Yeah, that wouldn't be
24 helpful, right? That'd be a real

1 problem?

2 MS. VANNI: Object to form.

3 BY MR. BUCHANAN:

4 Q. I mean, you had a consultant
5 come -- withdrawn.

6 You had a consultant come in
7 in 2010, in April, right? The Buzzeeo
8 group came in in April 2010?

9 A. April.

10 Q. We looked at that.

11 A. Right.

12 Q. They said, "There is no
13 suspicious order monitoring program," is
14 what they said, right?

15 A. That was their observation.

16 Q. Right.

17 A. Those were their words.

18 Q. They showed you the C.F.R.
19 They made a recommendation, right? They
20 said, "You need an SOP," right?

21 MS. VANNI: Object to form.

22 The document speaks for itself.

23 MR. BUCHANAN: I'm happy to
24 let it speak for all of us.

1 THE WITNESS: They said --

2 MR. BUCHANAN: I told you

3 I'd allow that to happen.

4 THE WITNESS: My

5 interpretation of what they said

6 is they said we need to improve

7 our program around order

8 monitoring.

9 BY MR. BUCHANAN:

10 Q. What they said, "There is no
11 suspicious order monitoring program in
12 place." You can agree that's what they
13 wrote and told the company in early 2010,
14 correct?

15 A. That's what they said in
16 2010, based on the way they would define
17 suspicious order monitoring.

18 Q. Right. And -- well, they
19 said you had no suspicious order
20 monitoring program in place. Yes or no?

21 A. That's what it says here.

22 Q. Thank you. They quoted you
23 the regulation. Yes or no?

24 A. They quoted the regulation.

1 Q. They said, "Although it was
2 stated" -- okay, do you understand that
3 to be referring to your people talking to
4 the Buzzeo folks, right?

5 MS. VANNI: Object to form.

6 BY MR. BUCHANAN:

7 Q. "Although it was stated that
8 sales are mainly to large wholesalers" --
9 is that your understanding, sir?

10 A. Right.

11 Q. The Buzzeo folks got that
12 information from your team at Par, right?

13 A. Presumably yes, they were
14 speaking to people at Par.

15 Q. Right. "Although it was
16 stated that sales are mainly to large
17 wholesalers, a program must be instituted
18 based on customer sales, volumes,
19 seasonal fluctuations, et cetera, with a
20 firm statistical analysis as the basis
21 for such a program."

22 Did I read that correctly,
23 sir?

24 A. You read -- that's what it

1 says.

2 Q. Okay. "It is further
3 recommended that the basis for
4 conducting" -- what? Due diligence.

5 Do you see that?

6 A. I see that.

7 Q. -- "of new and existing
8 customers and identifying and
9 investigating and clearing of reporting
10 suspicious orders be documented in an
11 SOP."

12 Did I read that correctly,
13 sir?

14 A. You did.

15 Q. Okay. And so we have now,
16 the rest of 2010 passes without an SOP,
17 right?

18 A. This appears to be the first
19 SOP that is specifically titled
20 "Suspicious Order Monitoring."

21 Q. All of 2011 passes without
22 an SOP, right?

23 A. As I said, this is the first
24 SOP that appears to be entitled

1 "Suspicious Order Monitoring." That
2 doesn't mean that Par wasn't complying
3 with the registration around identifying
4 potentially suspicious orders --

5 Q. And then in --

6 A. -- in the 2010-2011 time
7 frame.

8 Q. Then sometime around April
9 of 2012, you got around to getting an
10 SOP, huh?

11 MS. VANNI: Object to form.

12 BY MR. BUCHANAN:

13 Q. Do I have that right?

14 MS. VANNI: Object to form.

15 THE WITNESS: In April
16 of 2012, we published an SOP.

17 BY MR. BUCHANAN:

18 Q. Okay. And you published
19 that SOP, and, you know, we can agree
20 some 200 million units of pills and doses
21 and patches -- I guess it's not pills.
22 It's oral transmucosal fentanyl citrate
23 and syrups, are going out the door with
24 hydrocodone and fentanyl in 2010 and

1 2011, correct?

2 MS. VANNI: Object to form.

3 MR. BUCHANAN: Withdrawn.

4 Very confusing question.

5 MS. VANNI: Very.

6 BY MR. BUCHANAN:

7 Q. You told us earlier in
8 April 2012 you published that SOP. Yet
9 in 2010 and 2011 some 200 million dosage
10 units of fentanyl citrate and hydrocodone
11 went out the door, correct?

12 A. We sold those products in
13 2010 and 2011.

14 Q. Okay.

15 A. You're assuming that the
16 lack of -- the lack of an SOP meant that
17 those orders were not being looked at or
18 not being reviewed.

19 Q. You have not been able to
20 highlight any written procedure, any
21 documentation for the company that
22 preceded the April 2012 SOP, correct,
23 sir?

24 MS. VANNI: Object to form.

1 THE WITNESS: I don't have a
2 document.

3 BY MR. BUCHANAN:

4 Q. So could you describe for
5 us, sir, where in Exhibit 12 the company
6 describes how it's going to determine
7 what gets reported to the DEA?

8 A. If you can give me a minute
9 to review this.

10 Q. Sure. Let's just -- let's
11 just go to 1839.2 real quick.

12 A. 1839.2.

13 Q. We can agree under purpose,
14 policy, and responsibility, there's
15 nothing in here about reporting stuff to
16 the DEA, correct?

17 A. It says, "Define process of
18 suspicious order monitoring as determined
19 by sales operations that we are in line
20 with DEA requirements."

21 So if -- if the order needs
22 to be reported to DEA, that would be in
23 line with DEA requirements.

24 Q. Okay. So what orders, then,

1 are suspicious orders under your SOP for
2 suspicious order monitoring, sir?

3 A. Orders that would be deemed
4 of interest.

5 Q. Where are those? You're
6 looking -- it sounds like you are not on
7 1839.2. You are now on 18 point --

8 A. I'm just reviewing the
9 document.

10 Q. -- 1839.3. We can agree
11 1839.2 doesn't identify what a suspicious
12 order is, correct?

13 MS. VANNI: Object to form.
14 BY MR. BUCHANAN:

15 Q. Characteristics, quality.
16 We could agree?

17 A. It says, "Define a process
18 for suspicious order monitoring that's in
19 line with DEA requirements." That's what
20 it says.

21 Q. Okay. Let's go to 1839.3.
22 So what were you telling
23 your sales operations folks was a
24 suspicious order on 1839.3?

1 A. So what this is telling me
2 is that they're looking at orders that
3 are considered to be excessive. "If
4 quantities are higher than the average
5 transmission, it is questioned."

6 Q. Where are you, sir?

7 A. I'm on -- under procedure.

8 Q. Okay. What paragraph?

9 A. The second one. "Weekly
10 replenishment purchase orders are
11 analyzed by account service executives
12 versus customer provided usages. If
13 quantities are higher than the average
14 transmission it is questioned.

15 "The buyer is contacted to
16 review a written request, is asked as to
17 the reason for the increase. It is
18 reviewed to ensure it is correct and
19 warranted."

20 Q. Mm-hmm. And then what gets
21 reported to the DEA?

22 A. If there is not a reasonable
23 explanation for the order, and it was
24 deemed suspicious, then under the

1 regulations it would need to be reported
2 to DEA.

3 Q. Okay. And where is that?
4 I'm just trying to find that?

5 Can we agree, sir, nothing
6 in here spells out what and how it gets
7 reported to the DEA?

8 A. It doesn't seem to describe
9 that exact process. It seems to talk
10 more about monthly reports are generated
11 and sent to quality compliance for
12 submission to DEA on a quarterly basis.

13 Q. Okay. We can agree, sir, in
14 2010, I think your testimony was no
15 orders were identified as suspicious or
16 reported to DEA, correct?

17 A. We did not submit any
18 suspicious orders based on our review of
19 the orders.

20 Q. And not in 2011 or in 2012,
21 correct, sir?

22 A. Not to my knowledge.

23 Q. Okay.

24 A. After review and

1 investigation.

2 Q. Well, in fact, there was no
3 SOP in force until April of 2012,
4 correct?

5 MS. VANNI: Object to form.

6 THE WITNESS: Yes. No SOP
7 specifically entitled "Suspicious
8 Order Monitoring."

9 BY MR. BUCHANAN:

10 Q. Okay. And, in fact, please
11 tell the jury who had a responsibility
12 for evaluating orders once you had an
13 SOP.

14 Let's go to 1839.2. Do you
15 see the heading that says Responsibility?

16 Who had responsibility?

17 A. "Sales" -- "sales
18 operations/account services to monitor
19 applicable Par trade customer purchase
20 orders."

21 Q. Okay. So the sales group?

22 A. These aren't -- these aren't
23 salespeople. These are -- these are
24 people that -- these are more clerical

1 BY MR. BUCHANAN:

2 Q. This was put in force in
3 October of 2012, correct?

4 A. That's what it says.

5 Q. Okay. And then if we go to
6 dot -- and again it was -- go back again,
7 I'm sorry.

8 Again, it was written by the
9 same director of sales operations, right?

10 A. Right.

11 Q. And signed off by the --
12 excuse me, checked by the account
13 services executive, right?

14 A. Right.

15 Q. That's a different name than
16 last name.

17 And then we've got that same
18 Dino person, head of QA?

19 A. Yeah, he was -- he was head
20 of compliance for the -- for Par.

21 Q. Okay.

22 A. All of compliance.

23 Q. Okay.

24 A. Quality and DEA compliance.

1 Q. Okay. And well, let's look
2 at how this SOP evolved.

3 MR. BUCHANAN: Can we go to
4 .3.

5 BY MR. BUCHANAN:

6 Q. It says, "Reporting
7 suspicious criminal activities."

8 Do you see that?

9 A. I see that.

10 Q. Okay. "If criminal activity
11 is suspected, report the following" --
12 "report the following to the state
13 agencies that are" -- "that license the
14 facility, e.g., board of pharmacy and
15 Food and Drug Administration, as well as
16 Drug Enforcement Administration for
17 controlled substances within three days
18 of suspecting criminal activity."

19 Do you see that, sir?

20 A. I see that.

21 Q. Okay. We can agree, sir,
22 that your obligation and your promise as
23 a registrant, is to report orders of
24 unusual frequency, orders of unusual

1 A. I am not aware of a
2 suspicious order that had been identified
3 that would subsequently have been
4 reported to DEA.

5 Q. You're not aware of a single
6 order that was not shipped during this
7 period of time?

8 A. I'm not aware of an order
9 that was identified as suspicious and was
10 not shipped. That's not to say there
11 weren't any. I'm not aware of them.

12 MR. BUCHANAN: Let's take a
13 break.

14 THE VIDEOGRAPHER: Off the
15 record at 3:13 p.m.

16 (Short break.)

17 THE VIDEOGRAPHER: We are
18 back on the record at 3:32 p.m.

19 BY MR. BUCHANAN:

20 Q. Okay. Sir, I'm passing you
21 over a stack of exhibits. We'll go
22 through them in sequence. There's -- why
23 don't we start with what's been marked as
24 Exhibit Number 23.

1 (Document marked for
2 identification as Exhibit
3 Endo-Macrides-23.)

4 MR. BUCHANAN: Charles,
5 could you pass a copy for defense
6 counsel.

7 BY MR. BUCHANAN:

8 Q. For the record, it's
9 internally labeled as E-1051. If we can
10 pull up that on the screen. E-1051, sir,
11 is an e-mail to John Schultz, Mike
12 Reiney, Charles Propst, others.

13 Do you recognize any of
14 those names?

15 A. I recognize most of the
16 names.

17 Q. Okay. And a Mr. Mapes, a
18 former DEA agent, conducted an audit of
19 your facility in 2008 and provided a
20 report of that back to Qualitest
21 Pharmaceuticals.

22 Do you see that?

23 A. Right. Michael Mapes was
24 brought in to do an audit.

1 what -- excuse me, in 2008, that this is
2 what was required, right?

3 A. All companies were reviewing
4 the guidance by DEA to move in the
5 direction of statistical models --

6 Q. You still have to answer my
7 question.

8 A. -- to adapt their programs.

9 MS. VANNI: Objection to
10 form.

11 BY MR. BUCHANAN:

12 Q. You still have to answer my
13 question. So my --

14 A. Can you ask it again,
15 please.

16 Q. Yeah. My question to you,
17 sir, after you said, "In 2013, we engaged
18 with Cegedim to do that," I said, "So the
19 very consultant who told you in 2008 that
20 this is what was required was the
21 consultant you used in 2013 to implement
22 the statistically validated algorithm for
23 Qualitest, correct?"

24 A. We worked with them in 2013

1 to enhance the program and build us a,
2 you know, more advanced algorithm.

3 Q. Right. In fact you did that
4 after you sat down with the DEA in March
5 of 2013, correct?

6 A. I think I testified earlier
7 that we had identified areas to improve
8 our program throughout that period but as
9 early as 2011 when we had engaged Tracey
10 Hernandez to lead our DEA compliance.

11 Q. When did management first
12 approve and fund a statistically
13 validated algorithm to detect potentially
14 suspicious orders, sir?

15 MS. VANNI: Objection.

16 BY MR. BUCHANAN:

17 Q. Before or after the
18 March 2013 meeting with the DEA?

19 A. In 2013 we engaged with
20 Cegedim to develop the algorithm.

21 Q. After you met with the DEA,
22 correct?

23 A. Subsequent to March of 2013.

24 Q. Which means after, right?

1 that?

2 A. I recall there was a
3 communication to DEA.

4 Q. And after you cut off these
5 three retail pharmacies that you were
6 still selling to, Exhibits 33, 34, and
7 35, we can agree that you didn't report
8 them to the DEA, correct?

9 MS. VANNI: Object to form.

10 THE WITNESS: There's no
11 knowledge here that -- or
12 information that they were
13 reported to the DEA.

14 BY MR. BUCHANAN:

15 Q. Because in fact, you were
16 the person selling to them? You were
17 selling directly to people that were
18 problematic customers, right?

19 MS. VANNI: Object to form.

20 THE WITNESS: We were
21 selling to these customers.

22 BY MR. BUCHANAN:

23 Q. Please look at Exhibit 41,
24 sir.

1 (Document marked for
2 identification as Exhibit
3 Macrides-41.)

4 THE WITNESS: 41?

5 BY MR. BUCHANAN:

6 Q. Yeah. Exhibit 41, sir, is
7 excerpted from the company's
8 interrogatories that were prepared by the
9 company and counsel and produced to us in
10 the last two weeks.

11 It says suspicious orders
12 and --

13 MS. VANNI: This is a
14 demonstrative based on the --

15 MR. BUCHANAN: It -- it's a
16 demonstrative. But it is, in
17 fact, the entire chart as -- as
18 reflected in the interrogatory.

19 BY MR. BUCHANAN:

20 Q. These are, in fact, either
21 suspicious orders or customers reported
22 to DEA by Par Pharmaceuticals, as
23 disclosed in discovery responses to us,
24 sir.

1 We could agree, sir, looking
2 at this list, that you don't see any
3 reports to the DEA of any suspicious
4 orders or any suspicious customers prior
5 to the meeting with the DEA in March of
6 2013, correct, sir?

7 MS. VANNI: Objection.

8 THE WITNESS: All these
9 dates are after March of 2013.

10 MS. VANNI: I want to make
11 one more objection to the extent
12 that I don't -- I don't know
13 whether that interrogatory even
14 called for that information.

15 MR. BUCHANAN: It does. But
16 your objection is noted.

17 MS. VANNI: I also object to
18 completeness.

19 BY MR. BUCHANAN:

20 Q. We could also agree, sir,
21 that the pharmacies that were cut off by
22 the company in -- following the Texas
23 road trip, 33, 34 and 35, Big Tex,
24 Advanced Pharmacy, BZ Pharmacy, those are

1 ultimate end customer.

2 BY MR. BUCHANAN:

3 Q. UPS didn't have a
4 relationship with your customers,
5 correct?

6 A. UPS is our distribution
7 partner.

8 Q. My question to you, sir, is,
9 UPS -- you were UPS's customer, correct?

10 MS. VANNI: Object to form.

11 THE WITNESS: UPS --
12 correct. UPS is a third-party
13 distributor.

14 BY MR. BUCHANAN:

15 Q. Right. UPS did not have
16 visibility to your customers and did not
17 conduct due diligence of your customers,
18 correct, sir?

19 MS. VANNI: Object to form.

20 THE WITNESS: No UPS -- UPS
21 is the registrant for
22 distribution, for the distribution
23 license would be required to have
24 a suspicious order monitoring

1 program in place.

2 BY MR. BUCHANAN:

3 Q. My --

4 A. It would be the
5 responsibility of the client, in this
6 case Endo, to manage the customer
7 relationship.

8 Q. For you to manage your
9 customer, your Morris and Dickson, your
10 FW Kerr, your Top Rx, your BZ Pharmacies.
11 Those were your customers?

12 A. That's how -- yes, that's
13 how these relationships work.

14 Q. Right. And it was your job
15 to manage your -- and do -- manage and do
16 the due diligence on your customers,
17 correct?

18 MS. VANNI: Object to form.

19 THE WITNESS: The model here
20 is to outsource distribution. The
21 customer relationship, the
22 customer diligence is with Endo in
23 that case.

24 Now UPS, given the fact that